PACKAGE LEAFLET: INFORMATION FOR THE USER
Flutarzole®
50mcg/dose nasal spray suspension
Fluticasone propionate,

1. IDENTIFICATIONS OF THE MEDICINAL PRODUCT

1.1. Trade name

Flutarzole® nasal spray suspension 50mcg/dose.

1.2. Composition

Active substance: Fluticasone propionate
Excipients: Dextrose anhydrous, Avicel RC 591 (microcrystalline cellulose + carboxymethyl cellulose sodium), Phenethyl alcohol, Benzalkonium chloride, Polysorbate 80, Dilute hydrochloric acid, Water purified.

1.3. Pharmaceutical form

Nasal spray suspension

1.4. Quantitative composition

Each dose (spraying) contains 50 mcg fluticasone propionate.

1.5. Nature and content of the container

Each carton contains bottle of 16g (120 doses) with meter-pump and a leaflet.

1.6. Pharmacotherapeutic category

Corticosteroid.

1.7. Marketing Authorization Holder

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1.8. Manufacturer

Pharmaceutical Industry PROEL Epam. G. Koronis S.A.

2. WHAT SHOULD THE PATIENT KNOW ABOUT THIS MEDICINE

2.1. General information

Fluticasone propionate is an active topical corticosteroid, with a high therapeutic factor, based on the combination of potent anti-inflammatory action and the week suppression to the Hypothalamic-Pituitary-Adrenal axis (HPA axis), when administered topically in the nasal mucosa.

2.2. Indications

It is indicated for the prophylaxis and treatment of seasonal allergic rhinitis including hay fever. It is also indicated for the prophylaxis and treatment of perennial rhinitis in adults.

2.3. Contraindications

It is contraindicated to patients that are hypersensitive to any of the ingredients, to patients that suffer infection of respiratory tract, active or latent tuberculosis, stomach or duodenal ulcer and also to patients that are recovering recent surgical operation or trauma in nasal cavity.
Below are mentioned general contraindications of systemically administered corticosteroids:
A significant number of conditions and diseases are included in this section. Consideration of the expected therapeutic benefit versus the potential risk will affect the prescribing decision. These conditions and diseases include: gastro-duodenal ulcer, ocular herpes simplex, glaucoma, severe osteoporosis, diabetes mellitus, psychosis, immediately before or after vaccination, cardiovascular disease or hypertension with congestive heart failure, systemic mycosis, tuberculosis, severe nephropathy, infectious disease, hemorrhagic predisposition.

2.4. Special warnings and precautions for use

2.4.1. General

Topical infection: Infected nasal respiratory tracts should be treated with the suitable treatment without considering as contraindication the application of **Flutarzole®** nasal spray suspension. Expected therapeutic result will be delayed if the treatment with **Flutarzole®** nasal spray suspension is discontinued for few days.
Transition from systemic corticosteroid to **Flutarzole®** nasal spray suspension, should be monitored closely. As mentioned, expected therapeutic result will be delayed especially if the treatment is discontinued for very few days. It is important to mention that systemic corticosteroid should be gradually discontinued; in this case there will be and interval of concomitant administration of systemic corticosteroid and **Flutarzole®** nasal spray suspension. Although **Flutarzole®** nasal spray manages the seasonal allergic rhinitis, in cases of significant exposure to allergens, especially during summer, additional complementary treatment may be needed to manage the ocular symptoms.

Below are mentioned general warnings for systemically administered corticosteroids:
Long-term administration may cause suppression of HPA axis leading to adrenocortical function impairment. The severity of this depends on the dosage and the potency of administrated corticosteroid, the duration and the frequency of administration within the day, half-life and the longevity of the treatment. It is mentioned that suppressive action of corticosteroids to the HPA axis is more pronounced and prolonged when administered at night. In healthy subjects a dose of 1mg dexamethasone when administered at night, suppresses the secretion of the pituitary-adrenocorticotropic hormone of the pituitary gland for 24 hours. Sudden or abrupt reduction of corticosteroid dosage may cause “withdrawal syndrome” presented as acute adrenocortical failure with muscle weakness, hypotension, hypoglycemia, nausea, vomiting, agitation, myalgia, arthralgia.

2.4.2. Elderly

See section Posology and instructions of use

2.4.3. Pregnancy

Η χρήση του ρινικού εκνεφώματος **Flutarzole®** κατά τη διάρκεια της εγκυμοσύνης απαιτεί στάθμιση της ωφέλειας σε σχέση με τους πιθανούς κινδύνους που ενέχει η χορήγησή του.

2.4.4. Lactation

Flutarzole® nasal spray suspension may be used during lactation only if the expected benefit outweighs possible risks for mother and infant.

2.4.5. Children:

See section Posology and instructions of use

2.4.6. Effect on the ability to drive and use of machines:

There are no reports on the effect of corticosteroids in the ability to drive and use machines.

2.4.7. Special warnings about the excipients

None.

2.5. Interactions with other medicines or substances:

Caution is needed in co-administration of fluticasone propionate with other potent inhibitors of CYP3A4 such as ritonavir or ketoconazole, as there is increased risk of high exposure to corticosteroid.

Below are mentioned interactions for systemic use of corticosteroids:
Reduced corticosteroid action in co-administration with phenytoin, phenovarbital, ephedrine and rifampicine. Alcohol and non-steroidal anti-inflammatory may enhance ulcerative effect. Co-administration with diuretics may intensify hypokalemia, while with digitalis the risk of digitalis toxicity is highly increased. Corticosteroids also reduce or enhance the action of coumarin anticoagulants. In diabetic patients that receive insulin or anti-diabetic oral treatment, increase in the anti-diabetic treatment might be needed to control diabetes.

2.6. Posology and instructions of use

Only for nasal use.

- Adults and children older than 12 years for prophylaxis and treatment of seasonal allergic rhinitis.
  Two sprayings in each nostril once daily, preferably in the morning. In some cases the dose may be increased to two sprayings in each nostril twice daily. Maximum daily dose should not exceed four sprayings daily in each nostril. Duration of the treatment is usually 2-4 weeks, but the doctor will determine the course of the treatment according to patient's response.
- Elderly patients: Same as for younger adults.
- Children younger than 12years:
  For prophylaxis and treatment of seasonal allergic rhinitis in children 4-11 years old: One spraying in each nostril once daily preferably in the morning. In some cases the dose may be increased to one spraying in each nostril twice daily. Maximum daily dose should not exceed two sprayings in each nostril daily. Duration of the treatment should also not exceed two (2) weeks.

For maximum therapeutic result it is necessary to use the medicine regularly. It is possible that there is no effect. Maximum symptom relief will be achieved in 3-4 days of treatment.

2.7. Overdose - Management:

There no data available on the effect of acute or prolonged overdose with **Flutarzole®** nasal spray suspension. In healthy patients, intranasal administration of 2 mg fluticasone propionate twice daily for 7 days had no effect on HPA axis function.
Poison Center Athens, Tel: +30 210 7793777.

2.8. Possible side effects

No serious side effects have been reported with **Flutarzole®** nasal spray suspension. Similar to other nasal sprays, there are reports for burning sensation in the nose, dryness and irritation of rhino-pharynx, unpleasant taste and smell sensation, headache and even epistaxis.
There are also reports of hypersensitivity reactions like rash and edema in the face or tongue.

Very rarely have been reported cases of puncture of nasal septum when corticosteroid nasal sprayings are used.
There are no reports for systemic reactions when the recommended doses are used. In sensitive patients after prolonged treatment or administration of high dosages it is possible that the HPA axis is suppressed and even symptoms of Cushing's symptoms are presented.
Funfal infection may develop by Candida or Aspergillus, locally in nose, mouth or pharynx. Additionally it may occur ulceration of nasal mucosa, sneezing, hoarseness.
During or after transition from systemic to nasal corticosteroid treatment it is possible for systemic reactions to occur such as arthralgia, myalgia, and depression. Eosinophilic pulmonary infiltrates and adrenal insufficiency have been also described.

Below are mentioned side effects of systemically acting corticosteroids:
Both natural glucocorticoids as well as their synthetic derivatives cause undesirable effects of the same degree at equivalent doses. Thus, long term administration, primarily may result in significant undesirable effects from which the major ones are: iatrogenic Cushing's syndrome, sodium and water retention, hypokalemia, hypertension, negative nitrogen and calcium balance with osteoporosis, peptic ulceration, psychotic disturbances, raised intraocular pressure and glaucoma, cataract, susceptibility to infections and spread of inflammations, growth retardation in children, idiopathic intracranial hypertension, aggravation of diabetes, inhibition of adrenocortical function, masking of acute surgical abdomen (silent peritonitis in the event of perforation).

If you get any side effects, please talk to your doctor or pharmacist or any other health care provider or directly to the National Medicines Agency (284 Mesogion Av., 15562, Cholargos, Athens, Greece www.eof.gr).

2.9. What you should know in case you forget to take one dose

If you receive this medicine regularly and you forgot to take a dose, you should take it as soon as you remember. However if it is near the time to receive your next dose then do not get the missed dose, simply continue the treatment as planned.
Do not double doses.

2.10. What should the patient know about the expiration date

It is mentioned in inner and outer packaging.
Do not use if this date has expired.

2.11. Special warnings about the storage of the product

Shake gently before use.
Store at temperature below 25°C.

2.12. Date of last revision of this leaflet

14-12-2012.

3. INFORMATION FOR THE RATIONAL USE OF MEDICINES

- This pharmaceutical product was prescribed by your doctor to you, according to your medical history and condition. Do not pass the product to others or use it in any other condition even if the symptoms may appear the same and without receiving your doctor's or pharmacist's advice.
- If during treatment with this medicine you experience any problem or issue, contact immediately your doctor or pharmacist.
- If you have any questions regarding the information for this product, its use or about the medical condition that you suffer, you should ask your doctor or pharmacist.
- This product will be safe and effective if it is used exactly according to instructions provided.

- For your own safety it is highly recommended that you read carefully all information provided for the prescribed medicine.
- Do not store medicines in bathroom lockers, as the high temperature and the humidity may degrade the product which may be harmful to your health.
- Store the product in the original packaging.
- If your doctor instructed you to stop the use of this product, dispose the remaining product and do not use it.
- Do not keep the medicine you do not need any more or those that are expired.
- Keep all medicines in safe place out of reach and sight of children.

4. PRESCRIBING INFORMATION

This medicine is subjected to medicinal prescription.